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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,666	02/08/2002	Gyanendra Kumar	13172.0015U1	3290

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,666	KUMAR ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) *137 and 138* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on May 02, 2007 has been considered.

Status of the Application

2. Claims 1-136 are pending. Claims 137-138 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive for the reasons that follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingsmore et al. (US 6,921,642) in view of Baner et al. (Nucleic Acids Res., Vol. 26 922), page 5073-5078, 1998).

With reference to the instant claims 1-2, 30-34, 43-49, 107, 124-126, 133-136, Kingsmore et al. teach a method for detecting one or more analytes comprising (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see col. 41, lines 40-55); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see col. 41, lines 40-67); (d) incubating the rolling circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see col. 41, lines55-67, col. 42, line 39-51).

With reference to the instant claims 12-22, Kingsmore et al. teach that the method comprises circle linkers (capture docks), wherein circle linker comprises cleavable bond which could be a disulfide bond, hetero bifunctional succinimide bond (sulfo-GMBS) maleimide bond,

dihydroxy bond or amino linking group (reactive group) which can be cleavable by treatment with a reducing agent (see col. 14, lines 27-67, col. 15, lines 1-6, col. 30, lines 3-10).

With reference to the instant claims 23-29, 33-34, Kingsmore et al. also teach that the method comprises (i) plurality of reporter binding molecules are brought into contact with the one or more analyte samples (see col. 41, line 40-48, col. 44, line 39-46); (ii) plurality of analyte samples are brought into contact with the one or more reporter binding molecules (see col. 44, lines 39-46); (iii) at least one of the analyte samples comprise a protein or peptide, a lipid, glycolipid or proteoglycan (see col.11, line 1-15); (iv) at least one of the analytes is from a human source and a non-human source (see col. 31, line 54—55col. 37, line 4-15); and none of the analytes are nucleic acids (see col. 34, line 40-42);

With reference to the instant claims 31-32, 35, Kingsmore et al. teach that the method comprises capture agent(s) and analyte(s) associated with a solid support and the solid support comprises different reaction chambers or predefined regions (see col. 41, line 40-67); the said solid support comprises acrylamide, agarose, cellulose, nitrocellulose, glass, polystyrene or polyamino acids (see column 43, line 14-21);

With reference to the instant claims 36-42, Kingsmore et al. also disclose that the method comprises (i) bringing into contact at least one of the analyte samples with at least one accessory molecule affecting interaction of at least one of the analytes and at least one of the capture agents simultaneously with or following step (a) (see col .43, line 44-50); (ii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step (a) (see col. 43, lines 44-56); (iii) the accessory molecule is a protein kinase, a protein phosphatase, an enzyme or a compound (see col. 43, line 61-63); (iv) interaction of accessory

molecule of interest, with one or more analytes are test molecules of interest are detected (see col. 43, lines 64-67, col. 44, line 1-9);

With reference to the instant claims 43-75, Kingsmore et al. also teach that the method comprises (i) one or more first analyte samples and one or more second analyte samples, one or more first reporter binding molecules, one or more second reporter molecules, wherein each different reporter binding molecule is different and each different rolling circle primer primes replication of a different amplification target circle and produces a different tandem sequence DNA (see col. 44, line 5-29); (ii) the tandem sequence DNA corresponding to one of the analyte samples produced in association with an analyte capture agent is in the same location on the solid support as tandem sequence DNA corresponding to the same analyte and produced in association with the matching second analyte capture agent, wherein presence or absence of the same analyte in different analyte samples is indicated by the presence or absence of corresponding tandem sequence DNA (see col. 44, line 30-38); (iii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step(a) (see col. 43, line 57-60); (iii) the accessory molecule is a protein kinase, a protein phosphatase, an enzyme or a compound (see col. 43, line 61-63); (iv) the accessory molecule is an analog and facilitates interaction of at least one of the analyte capture agents (see col.43, line 64-67, col. 44, line 1-4); accessory molecule is at least 20%, 50% , 80%, 90% pure and is associated with solid support (see col. 43, line 22-35);

With reference to the instant claims 76-83, Kingsmore et al. teach that the method comprises modified form of analyte wherein at least one or more analyte capture agents interacts directly or indirectly with the modified analyte, wherein the modification is post-translational

modification, that is phosphorylation or glycosylation (see col. 11, line 7-15); detection of tandem sequence DNA is accompanied by mixing a set of detection probes under conditions to promote hybridization, wherein plurality of different tandem sequence DNAs are detected separately or simultaneously via multiplex detection (see col44, line 39-67, col. 45, line 1-32); detection probes are labeled using combinatorial multicolor coding (see col. 28, line 47-67, col. 29, line 1-12); the method further comprises brining into contact a secondary DNA strand displacement primer and the tandem sequence DNA, and incubating under conditions that promote (i) hybridization between the tandem sequence DNA and the secondary DNA strand displacement primer, (ii) replication of the tandem sequence DNA (see col. 19, line 38-60, col. 30, line 54-67, col. 31, line 1-3, col. 21, line 51-67);

With reference to the instant claims 85-106, 127-132, Kingsmore et al. teach that the method comprises detection labels as fluorescent moieties including fluorescent quenchers, which are incorporated into nucleic acids during amplification (see col. 15, lines 55-67, column 16, lines 1-18).

With reference to the instant claims 108-112, Kingsmore et al. further teach that the method comprises (i) treating one or more analyte samples so that one or more samples modified (see col. 26, line 9-12); bringing into contact one or more analytes and one or more arrays wherein each array comprises a set of analyte capture agents, a set of accessory molecules, each interacting directly or indirectly with an analyte, contacting one or more reporter binding molecules under conditions promoting interaction of the specific binding molecules analytes, analyte capture agents and accessory molecules, replicating with rolling circle replication primers to form tandem sequence DNA (see col. 26, line 13-40); (ii) comprises solid support

wherein components are immobilized to the solid support at a density exceeding 400 different components per cubic centimeter (see col. 21, line 6-16);

With reference to the instant claims 113-123, Kingsmore et al. also teach that the method comprises (i) analyte capture agents as peptides (see column 13, lines 59-66) immobilized on a solid support comprising 20% to 99% pure capture agents (see col. 15, line 6-21); (ii) comprises peptide, antibodies (antibodies are made up of short peptides) which comprise amino acids of about 20 amino acids (see col. 13, line 61-67, col.14, line 1-13).

However the method in the patent ('642) did not specifically disclose a decoupling step to dissociate amplification target circle associated with analytes form specific binding molecule.

Baner et al. teach a method signal amplification of padlock probes by rolling circle replication, wherein Baner et al. teach that the method utilizes circularizing oligonucleotide probes or padlock probes in rolling circle amplification to enhance signal amplification (see page 5075, col. 1, paragraph 1 under results section), wherein Baner et al. disclose that the circularized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with a step of decoupling amplification target circle as taught by Baner et al, to develop a sensitive method for the detection of multiple analyte(s) because Baner et al. explicitly

taught the use of padlock probes in rolling circle amplification, and circularized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3). Thus an ordinary skill in the art would have a reasonable expectation of success that the modification of the method taught by Kingsmore et al. in a manner as taught by Baner et al. would result in an enhanced signal amplification for detecting one or more analytes and such modification of the method is considered as obvious over cited prior art.

Response to arguments:

4. With regard to the rejection of claims 1-136 under obviousness type double patenting, applicants' arguments and terminal disclaimer are fully considered and the rejection is withdrawn herein in view of the terminal disclaimer.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Prabha Chunduru 7/2/07
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